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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,794	07/28/2003	Robert I. Rudko	LE-205J	4536

7590 12/01/2005
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Waltham, MA 02451-1018

EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/628,794

Applicant(s)

RUDKO ET AL.

Examiner

Michael Peffley

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16-18 is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Applicant's arguments, received August 19, 2005 have been fully considered by the examiner now of record. The following is a complete response to the August 19, 2005 communications.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaafar et al (2002/0045848).

As asserted in the previous Office action, Jaafar et al disclose a device comprising a lumen (16) including a steerable tip portion (36) extending from a joint portion (i.e. distal end of sheath 16 after the balloon). A registration means (balloon - 21) holds the joint portion in place and a source of ablative energy (laser - 12) is in communication with the lumen and delivered to the tip portion via an optical fiber (32).

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al (5,366,490).

Edwards et al also disclose a device comprising a lumen (14) having a steerable distal tip (i.e. stylet – 36) extending from a joint portion (34). A registration means, including balloons (30,32) hold the joint member in place during movement/treatment with the tip member. The tip member may include various devices, including RF

Art Unit: 3739

electrodes and laser fiber optics (col. 5, lines 21-24) and is connected to an ablative laser source (see Abstract). The second balloon (30) is deemed to act in concert with the first balloon as a barrier (i.e. tissue is trapped between the two balloons), and the device is deemed to be inherently capable of being used in the manner described in the claims (i.e. in the heart) even though there is no explicit recitation of such a use in the Edwards et al device.

Allowable Subject Matter

Claims 16-18 are allowed. Applicant's arguments with respect to claim 16 are deemed persuasive. In particular, Stevens ('214) fail to disclose the step of delivering ablative energy through the lumen and steering the distal tip to resect tissue as set forth in the claims. Rather, Stevens provides mechanical cutting blades, and mechanical cutters would not be deemed "ablative" energy sources by those of ordinary skill in the art.

Response to Arguments

Applicant's arguments with respect to claims 1-15 have been considered but are not persuasive.

Regarding the Jaafar et al reference, applicant contends on page 4 of the response that Jaafar et al fail to disclose an ablative energy source since the tip member is designed to scatter radiation in different directions during use. This argument is not deemed particularly suited to the claim language as presented in the claims. The claims merely recite "a source of ablation energy" that is connected to the device. The examiner maintains that the UV laser source is, indeed, an ablative energy

source. While the light may be delivered from the distal tip in a manner not conducive to ablation (i.e. scattered), it still is providing ablative energy along the fiber optic. That is, if a lens were placed at the distal tip of the fiber optic to focus the exact same energy, the device would function to ablate tissue. As such, the examiner maintains that the energy source delivers ablative energy which is subsequently modified by the distal tip member to scatter the light energy for the treatment of tissue.

Applicant continues to assert that Jaafar et al also fail to disclose a "registration means" because the balloon serves to occlude an artery (applicant's response, page 5). Again, this argument is not deemed persuasive. Regardless of the function of occluding an artery, the Jaafar et al balloon clearly also serves to stabilize the device within the artery and inherently and necessarily acts as a registration means to hold the distal end of the device within the artery while the more distal, steerable portion is used to treat tissue.

Concerning the Edwards et al reference, applicant points out on pages 5 and 6 of the response that Edwards relies on a guide housing and a stylet positioning block to control the stylets. The examiner agrees that this is an accurate depiction of the Edwards et al device, but maintains that the device still contains the structure recited in the rejected claims. That is, the stylet distal tip is steerable in that the stylet block controls the direction of the stylet as it is advanced from the device to treat tissue. Applicant continues to argue on pages 6 and 7 of the response that Edwards et al do not disclose an ablative energy source, and that reference (150) in Figure 12 is merely directed to a control console. The examiner maintains that the Edwards et al

Art Unit: 3739

specification makes it abundantly clear that ablative energy is used to treat the prostate tissue. See, for example, see col. 2, lines 37-46; col. 2, lines 62-64; and col. 4, lines 31-34. The control console (150) of the Edwards et al system is deemed to contain all the necessary connected hardware (i.e. energy source, control electronics, etc.). Although Edwards et al do not explicitly state that the ablative energy source is within the console (150), the Edwards et al reference is replete with explicit statements that the device is connected to a source of ablative energy (including laser, microwave, or RF energy) and it is merely intuitive that such an energy source would be located within the control console, particularly since Edwards et al don't disclose a separate energy source external to the control console. Moreover, even if the ablative energy source were external to the control console, the examiner maintains that the control console controls the delivery of the ablative energy and would still act as a "source", albeit an intermediate source or "substation".

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

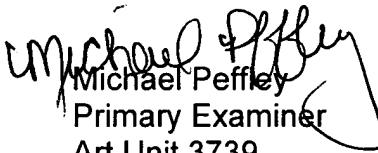
Art Unit: 3739

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

mp
November 23, 2005